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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,466	08/16/2001	Larry D. Paskar	39868/25551	3794

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,466

Applicant(s)

PASKAR, LARRY D.

Examiner

Mark W Bockelman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Mark Bockelman
MARK BOCKELMAN
APR 11 2001

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 8, 14, 16, 17- 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "mathematically rotating" in claims 8 and 17 is unclear in meaning. It is unclear how it differs from simple rotation. The examiner is at a loss as to how a curve defines a volume, it would have to be an enclosed circle and the examiner does not see where applicant has support for such. IT is not understood how it overlaps the larger curve. The examiner requests a written demonstration of these claim language in the next response. It is also unclear as to how a curve has an axis???? An axis is a straight line. With respect to claims 14 and 16 it is unclear as to whether the term "separated in operation" is positively reciting the operation or not. For purposes of applying art, the examiner considers it not to be a step. The examiner encourages the applicant to utilize language from the original specification or provide corresponding language and description of its meaning in the current version of the specification. No new matter may be added and applicant needs to demonstrate support for the newly introduced language.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5, 7-12, 14, 16- 18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz..

In regard to claim 84, Sylvanowicz teaches an inner catheter (surgical element) that is situated within an outer catheter both with preformed curves the entire assembly to be inserted into the body. Applicant claims that the inner catheter is "positioned" in an out of plane configuration with respect to the outer catheter. The examiner considers this to include any such positioning, be it momentarily or permanently. The examiner notes that since since Sylvanowicz rotates the inner catheter 180⁰ (see column 6 lines 3-8) with respect to the outer catheter, the inner catheter at some point will be "positioned" in an out of plane configuration. It is impossible for Sylvanowicz to change the combination catheter configuration from figure 7 to figure 8 in by rotation as taught in his specification without having the inner tip member 21 pointing in a direction into, or out of the page. On the other hand, Sylvanowicz does not explicitly teach that the inner catheter is "positioned" in a "fixed" manner so that the inner catheter curve is fixed out of plane with respect to the outer catheter as specified in claim 85. However, the examiner bases his inherency arguments on two passages. First, the examiner notes that at column 6 lines 10-17 Sylvanowicz teaches that a fitting that is adjustable to seal

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against the inner catheter in order to seal the inner catheter. In the use of such a gasket, a fairly tight squeezing force would be employed that would create a friction fit. The examiner considers such a friction fit to be a fixating step even though the user may still be able to turn the inner catheter with respect to the outer, without such a force applied, they are fixed. Along this line of reasoning, column 7 lines 64-66 notes that there is resistance to rotation albeit lessened by using the embodiment of figure 12. (It is noted that Cho USPN 5,109,830 uses a similar device for locking) Secondly the examiner notes column 7 lines 20 -30. "Among the advantages of this embodiment of the invention is that the orientation of the distal tip 54 may be varied by rotating the proximal end of the catheter 50 by the fitting 58. Thus, the inner catheter may be rotated along the longitudinal axis so that it is directed selectively toward the left coronary ostium or the left coronary ostium". While the Sylvanowicz disclosure teaches the rotation of *approximately* 180⁰, the examiner notes that the coronary arteries are not in the same plane within the descending aorta and would require some out of plane fixation before injection of contrast media. (See figure 5 of USPN 5,195,990) For placement of the catheter tip "In this embodiment, it is not necessary to rotate both the inner catheter and outer sheath portions of the catheter assembly". (column 7 lines 61-63). Clearly Sylvanowicz teaches rotating the inner catheter relative to the outer sheath without rotating the outer sheath. The examiner submits that if the inner catheter and outer sheath have curved portions within the same plane for one of the configurations (most likely the left coronary ostium) than the second configuration is necessarily out of plane (for the right coronary ostium). Thus, the examiner considers it inherent that the

inner catheter is oriented out of plane when both the left and right coronary arteries are accessed in the manner taught by Sylvanowicz (i.e. by rotating the inner member) or would have been obvious since they are not at 12:00 and 6:00 with respect to one another. "Fixing" them merely requires leaving them in place while the angiography is performed since the gasket and tightener of Sylvanowicz would grip much in the same as applicant's clamp member 103. The sylvanowicz device is capable of meeting the limitations concerning the spacing between the smaller and larger curves.

1. Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Petruzzi (alone or in view of Cho USPN 5,109,830).

Petruzzi teach a method of inserting and positioning an inner catheter as well as a surgical element within the lumen of an duodenoscope that has remote control means thereon. The inner catheter assumes the shape of the scope as it is bent along its length and its distal curved portion assumes its own curved shape when extended and assumes the shape of the scope when retracted. Petruzzi shows how complex bends with in the duodenum are negotiated during insertion and how the distal tip of the catheter can be reshaped by bending the catheter as well as by using actuator 92.

It would also seem inherent that both the inner catheter as well as the instrument of Petruzzi are rotatable about the longitudinal axis and done in an out of plane manner since such would facilitate the access of the various body lumens. If not inherent, Cho specifically teaches that to rotate surgical instruments in various configurations and fix

them in with respect to a duodenal scope was known. The Petruzzi device is capable of meeting the limitations concerning the spacing between the smaller and larger curves.

2. Claims 1-18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cho USPN 5,109,830.

Cho teaches the positioning of a bent fiber optic device within the lumen of a patient. It is seen that the fiber optic 5 can be positioned and rotatably fixed with respect to the guiding tube which may be a duodenal scope as shown in figure 7. Although the specifics of the duodenal scope are not disclosed, the examiner uses Petruzzi to show their conventional structure including the multidirectional bending wires. Essentially, the Petruzzi reference is used to fill in the structure that is inherent to Cho. The ability to reconfigure the fiber optic is apparent and the method steps are believed to be inherent or obvious to the Cho disclosure. Cho using conventional duodenoscope structure as disclosed by Petruzzi, contains all of the structure disclosed by applicant. Applicant's methods are nothing more than inherent or obvious steps required for accessing the various body lumens. The Cho device is capable of meeting the limitations concerning the spacing between the smaller and larger curves.

3. Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over D'Amelio et al et al USPN 4,659,195.

D'Amelio et al shows applicant's method and device for reforming curves See particularly figs 13-16 and 19 for forming curve members. Element 38 is used to rotationally fix the inner device with respect to the outer device. D'Amelio et al teaches the device has medical applications which instructs the reader that the method shown for engines could be used for body cavities. Therefore the examiner considers the teachings to be within the reference. If not , it would be obvious to carry out such methods within the body of a patient. The D'Amelio device is capable of meeting the limitations concerning the spacing between the smaller and larger curves.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No.5,304,131. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims merely delete patentable limitations from the patent claims so as to make them broader in scope. The delete of limitations from a claim is considered obvious to any one of any skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-305-3591 for regular communications and (703)-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB
March 25, 2002


MARK BOCKELMAN
PRIMARY EXAMINER